Annex

2 References

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS
2. BIBLIOGRAPHY
3. FDA SUPPORTING DOCUMENTS

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS

The *Food Code* makes frequent reference to federal statutes contained in the United States Code (USC) and the *Code of Federal Regulations* (CFR). Copies of the USC and CFR can be viewed and copied at government depository libraries or may be purchased as follows.

(A) Viewing and Copying the USC or CFR

(1) Government Depository Library

The USC and CFR are widely available for reference and viewing in some 1400 "depository libraries" located throughout the United States. *A Directory of U.S. Government Depository Libraries* is published by the Joint Committee on Printing of the United States Congress and is available through the Superintendent of Documents, U.S. Government Printing Office. This publication lists all depository libraries by state, city, and congressional district.

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The CFR are available on-line in downloadable form through the Internet World Wide Web information system. The source is:

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(B) Purchasing Portions of the USC or CFR

Persons wishing to purchase relevant portions of the USC or CFR may do so by writing: or by calling:

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(202)512-1800 from 7:30 a.m. to 5:00 p.m. eastern time, Monday-Friday (except holidays. Orders may be charged to Discover/Novus, MasterCard or Visa.

(C) USC as it Relates to the Code Definition of "Adulterated"

This language has been retyped as accurately as possible and inserted in the Food Code Annex for informational purposes. For legal purposes, use only language taken directly from the United States Code (USC).

21 USC Sec.342
Title 21 - Food and Drugs
Chapter 9 - Federal Food, Drug and Cosmetic Act
Subchapter IV - Food

ADULTERATED FOOD

Sec. 402 [342]

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or

contains (*i*) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and -

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced and delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on a confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that -

(A) presents a significant or unreasonable risk of illness or injury under -
(i) conditions of use recommended or suggested in labeling,
or
(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;
(C) The Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or
(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a) (1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.
In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.
(2) Before the Secretary may report to a United States attorney a violation of paragraph (1) (A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.
(g) Dietary supplement: manufacturing practices
(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).
(2) the Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.

(As amended by 104th Congress, Fall, 1996.)

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Chapter 1 Purpose and Definitions

1-201.10 Statement of Application and Listing of Terms

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2-303.11 Prohibition. (Jewelry)
2-304.11 Clean Condition. (Outer Clothing)
2-401.11 Eating, Drinking, or Using Tobacco.*
2-402.11 Effectiveness. (Hair Restraints)

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Chapter 4 Equipment, Utensils, and Linens

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Chapter 5 Water, Plumbing, and Waste

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3. FDA SUPPORTING DOCUMENTS

FDA has developed and issued the following guidance documents. A brief summary for each document is provided.

A. (Draft) Recommended National Retail Food Regulatory Program Standards
B. FDA Procedures for Standardization and Certification of Retail food Inspection/Training Officers
C. (Draft) Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level
D. Food Establishment Plan Review Guidelines
E. Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors

A. (Draft) Recommended National Retail Food Regulatory Program Standards

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/ret-toc.html and was formulated from ideas and input by federal, state, and local regulatory officials, industry, trade and professional associations, academia, and consumers. The purposes of these standards are:

- To serve as a bench mark to retail food regulatory program managers in the design and management of a retail food program;
- To provide a means of recognition of programs meeting these standards;
- To promote uniformity in retail food programs to reduce the risk factors known to cause foodborne illness;
- To provide a foundation for the food regulatory program that is focused on the risk factors and other factors that may contribute to foodborne illness; and

- To promote, through the management of a retail food regulatory program, the active managerial control in the retail establishment of all the factors that may cause foodborne illness.

Further purposes of these standards are to serve as a guide to regulatory retail food program managers in the design and management of a retail food program and to provide a means of recognition for those programs that meet these standards.

The intent in the development of these standards is to establish a basic foundation in design and management of a retail food program. Program management may add additional requirements to meet individual program needs.

The standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause foodborne illness as well as other factors that may contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness.

B. Procedures for Standardization and Certification of Retail Food Inspection/Training Officers

This document can be found at the web site http://vm.cfsan.fda.gov/~ear/rfi-toc.html. This is a procedure that integrates the assessment of an individual's knowledge, skills, and abilities in a manageable number of inspections while preserving the quality and integrity of the process. At the same time, we continue to learn from our experiences in applying it and remain open to improving these Procedures based on your experiences and feedback.

As they are written, the Procedures address the situation wherein an FDA Standard is assessing a CANDIDATE who is not employed by FDA. For example, Paragraph 3-301(C) mentions but does not require recording citations (i.e., identifying the codified provision that relates to each observed violation). Since jurisdiction's codification systems (numeric or alphanumeric) are usually different from the system in the FDA Food Code, the utility of that practice would be minimal in an FDA-to-jurisdiction field exercise. However, within a jurisdiction where the same Code is in use, the practice could be useful in reinforcing diligence in ensuring that violations listed during inspections are, in fact, soundly based in regulation.

FDA invites and encourages jurisdictions to use these Procedures in their internal Standardization and Certifications and to add dimensions that promote uniformity such as citing codified provisions, as discussed above. With a few language changes, the document can be custom-tailored to fit individual jurisdictions and serve as their procedures. As with other documents provided as guidance for applying regulatory requirements in the retail sector, these Procedures are in the "public domain" and we encourage their duplication and use.

C. (Draft) Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/hret-toc.html. FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. It recognizes that there are differences between using HACCP at retail and in food manufacturing. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system.

This document is intended to serve as a guide in the writing of a simple plan based on HACCP principles that can be used to manage food safety. It is very important to understand that this Guide is intended to assist industry's voluntary implementation of HACCP principles. It is not meant to stand alone, but instead should be used together with advice from and in consultation with your federal, state, local, or tribal food safety regulatory authority. The regulatory authority is an important resource for reviewing your food safety management system. Regulatory food safety professionals can provide important information for the public health rationale for controlling a particular hazard. Users of this document also need to consult and use the latest edition of the FDA Food Code since many of its requirements are not reproduced here but constitute a fundamental program that is prerequisite to implementing a HACCP program.

Hazard Analysis Critical Control Point (HACCP) is a common sense technique to control food safety hazards. It is a preventive system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards. HACCP is not a stand alone program but is one part of a larger system of control procedures that must be in place in order for HACCP to function effectively. These control procedures are prerequisite programs and are discussed more in Chapter 4.

The success of a HACCP program is dependent upon both people and facilities. Management and employees must be properly motivated and trained if a HACCP program is to successfully reduce the risk of foodborne illness. Education and training in the principles of food safety and management commitment to the implementation of a HACCP system are critical and must be continuously reinforced. Instilling food worker commitment and dealing with problems such as high employee turnover and communication barriers must be considered when designing a HACCP plan.

Successful implementation of a HACCP plan is also dependent upon the design and performance of facilities and equipment. The likelihood of the occurrence of a hazard in a finished product is definitely influenced by facility and equipment design, construction, and installation that play a key role in any preventive strategy.

The Agency recognizes that this document has areas that need to be further clarified and developed with broader input and based on industry’s experiences with the practicalities of

integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

D. Food Establishment Plan Review Guidelines

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/previntr.html. This food establishment Plan Review document has been developed for the purpose of assisting both regulatory and industry personnel in achieving greater uniformity in the plan review process. It is the result of a joint effort by FDA and the Conference for Food Protection.

Plan review of food service establishments, retail food stores, and all other food operations, must be maintained as a high priority by all regulatory food agencies for both new and existing facilities.

This document has been developed to serve as a guide in facilitating greater uniformity and ease in conducting plan review whether your position is a regulator or an industry person wishing to build or to expand. You need not be an expert to effectively complete this process.

A good review of plans helps to avoid future problems. By listing and locating equipment on floor plans and diagramming specifications for electrical, mechanical and plumbing systems, potential problems can be spotted while still on paper and modifications made BEFORE costly purchases, installation and construction.

Food establishment plan review is recognized as an important food program component that allows:

-- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
-- Industry to establish an organized and efficient flow of food.
-- Regulatory agencies to eliminate code violations prior to construction.

E. Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/retrsk.html. The 1996 report "Reinventing Food Regulations" [National Performance Review] concluded that *foodborne illness caused by harmful bacteria and other pathogenic microorganisms in meat, poultry, seafood, dairy products, and a host of other foods is a significant public health problem in the United States*. For years regulatory and industry food safety programs have been designed to minimize the occurrence of foodborne illness. There is, however, a lack of a national baseline on the occurrence of foodborne disease risk factors.

This project is designed to establish a national baseline on the occurrence of foodborne disease risk factors within the retail segment of the food industry. This report presents the methodology used to establish a baseline and reports the results of the data collected. The report is provided to regulators and industry with the expectation that it will be used to focus greater attention and increased resources on the control of foodborne illness risk factors.